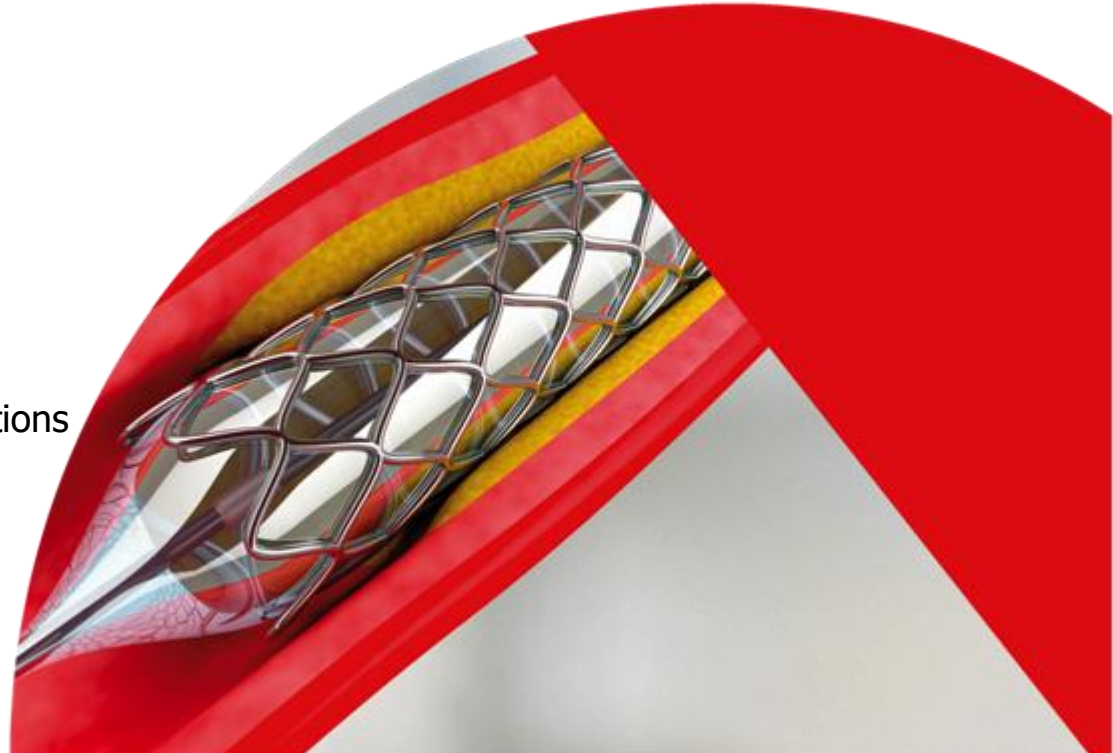
Enhanced PMCF

Ronald Rakos, PhD

The New EU Medical Device and IVD Regulations

August 29-30, 2017



Enhanced PMCF

PMS & PMCF - Articles 2 and 83

Article 2 Definitions – "post market surveillance"

all activities carried out by the manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from their devices placed on the market, made available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions;

Post-market Surveillance System, Article 83

For each device the manufacturer shall plan, establish, document, implement, maintain and update a post-market surveillance system (risk based)
PMS shall… actively and systematically gather record and analyze data on the quality performance and safety throughout the lifetime of the device

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PMS & PMCF - Articles 83-86, Annex XIV, Part B

Post-market Clinical Follow-up (Annex XIV, Part B)

- PMCF shall be a continuous process that updates the clinical evaluation and shall address the post-market surveillance plan. PMCF shall proactively collect and evaluate clinical data from the use of the device (CE marked)… with the aim of confirming the safety and performance throughout the expected lifetime… ensuring continued acceptability of identified risks and detecting emerging risks on the basis of factual evidence.
- PMCF shall be perform according to the PMCF plan
- The PMCF plan shall specify methods/procedures for **proactively** collecting clinical data with the aim of…
    - confirm the safety and performance throughout the expended device lifetime
    - identify previously unknown side-effects and there monitoring
    - identify and analyze emergent risks

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PMS & PMCF - Articles 83-86, Annex XIV, Part B

The PMCF plan shall include…

- references to relevant parts of the CER and Risk analysis
- objections of the PMCF
- an evaluation of the clinical data of equivalent or similar devices
- Reference to CS, harmonized standards as appropriate and guidance on PMCF
- detailed and **adequately justified time frame** for PMCF activities including the analysis of data and reporting
  - Often these timelines are excessively long; how can a PMCF study identify emerging risks if it does not start immediately?

The PMCF report shall contain the analysis of the findings and should be part of the CER and TF

The PMCF evaluation report shall be considered in the clinical evaluation and any preventative and/or corrective actions shall be implemented

Post Market Surveillance

QMS

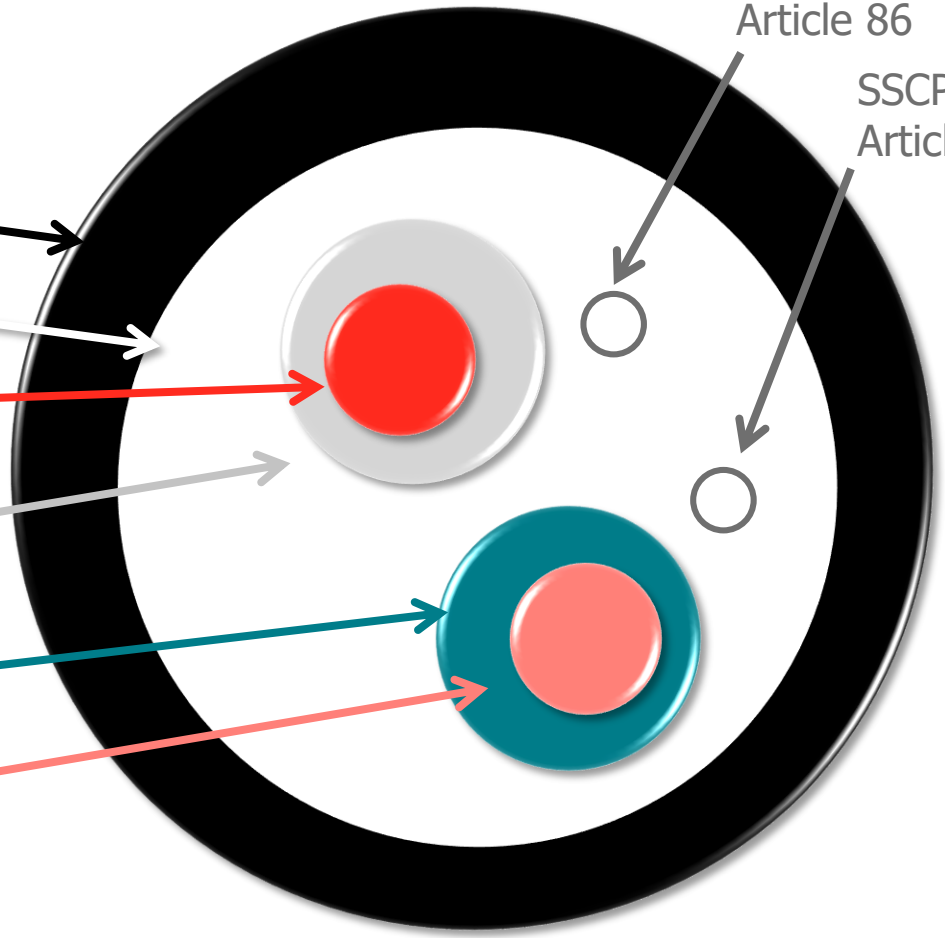
PMS
Article 83

Vigilance
Article 87-90

Reactive PMS

Proactive PMS

PMCF
Annex XIV



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Applies to every class of device under every route of conformity.

Periodic Safety Update Report – Article 86

- **Article 86 – PSUR:**
  - Conclusions of the benefit risk determination
  - Main findings of PMCF
  - Volume of Sales
  - Estimate of the Population that use the device
  - Where practicable usage frequency of the device

- Manufacturers of class IIb and III devices shall update the report at least annually.
- Manufacturers of class IIa devices shall update the report when necessary and at least every two years.
- Manufacturers of devices in class III **or** implantable devices shall submit reports by means of the electronic system to the notified body.

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Technical Documentation on PMS – Annex III

Information

- FSCA
- PSUR
- Information on similar devices
- Trend reporting
- Literature, Databases, Registries
- Complaints, User & Economic Operator Feedback
- Incidents

Plan

Proactive, systematic process to collect information to characterize, compare and assess the device

Clear, organized, readily searchable and unequivocal

Defines indicators & threshold values for risk benefit analysis

Defines complaint analysis methods including statistical analysis

Methods & protocols for trend reports

Procedures to identify, initiate & trace CAPA

Methods & protocols for CA, NB Economic Operator communication

Includes PMCF plan per Part B Annex XIV or justification if N/A

Report

Class IIa, IIb & III
Periodic safety Update Report article 86

Class I
Post Market Surveillance Report article 85

Technical Documentation Annex XIV Part B PMCF evaluation report

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Thank You!